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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/247,874	02/10/1999	GORDON W. DUFF	MSA-004.01	8151
30623	7590	03/10/2004	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			SCHNIZER, RICHARD A	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/247,874

Applicant(s)

DUFF ET AL.

Examiner

Richard Schnizer, Ph. D

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 34 and 46-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 34 is/are allowed.
- 6) ☐ Claim(s) 46-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/26/04 has been entered.

Claims 34 and 46-64 are pending and under consideration in this Office Action.

Specification

The disclosure is objected to because of the following informalities: The brief description of the drawings does not identify Figures 1A-1D or 2A-2D, and instead refers only to Figures 1 and 2.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46-64 are indefinite because it is unclear what is intended by "the nucleotide corresponding to the nucleotide at position 8845 of SEQ ID NO:2". More specifically, it is unclear what is meant by "corresponding to". It is unclear how these nucleotides are intended to correspond. Must they be the same nucleotide, or is any polymorphic nucleotide acceptable? Because it is unclear what is intended by "corresponding to", the phrase "the nucleotide corresponding to" also lacks proper antecedent basis. As discussed more fully below, it is suggested that the phrase "the nucleotide corresponding to the nucleotide at" should be deleted.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to the genus of nucleic acids comprising fragments of SEQ ID NO:2, that also comprise a certain fragments of SEQ ID NO:2. The essence of the invention is a polymorphism (a G to C transversion) that occurs at base 8845 of SEQ ID NO:2. This polymorphism is located in a 3' untranslated exon in a human IL-1beta gene. SEQ ID NO:2 is a genomic sequence of 9721 bases comprising almost 2 kb of 5'

untranscribed sequence, the transcribed region of the IL-1beta gene (about 7 kb), and about 800 bases 5' to the polyadenylation site. The claimed genus embraces any variant of SEQ ID NO:2 that may occur, as long as it comprises an unspecified nucleotide corresponding to the nucleotide at position 8845 of SEQ ID NO:2. Thus the claimed genus comprises allelic variants such as other single base polymorphisms that occur in the IL-1beta gene, splicing variants, and other functional variants of the IL-1beta gene.

The written description requirement for genus claims may be through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

The specification discloses a single polymorphism in SEQ ID NO:2 by reduction to practice. The specification does not disclose by reduction to practice or relevant identifying characteristic any other polymorphism within SEQ ID NO:2. As such one of skill in the art could not conclude that Applicant was in possession of the genus of nucleic acids comprising position 8845 of SEQ ID NO:2. This rejection can be overcome by substituting the words "consisting of" for the word "comprises" in claim 46.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 46 and 53 are rejected under 35 U.S.C. 102(b) as anticipated by Clark et al (GenBank Accession No. X04500, 6/1997).

The claim is drawn to isolated nucleic acids comprising between about 100 and 7000 consecutive nucleotides of SEQ ID NO:2, wherein the nucleic acid "contains the nucleotide corresponding to the nucleotide at position 8845 of SEQ ID NO:2. A review of SEQ ID NO: 2 shows that this nucleotide is 'C'. The claim does not stipulate where the in the fragment the C must be located, and so embraces any sequence comprising 100-7000 bases of SEQ ID NO:2 that also comprises a C.

Clark teaches the isolation and sequencing of a human prointerleukin 1 beta allele. The sequence is 9721 bases in length and is 100% identical to SEQ ID NO:2 except for the polymorphism at position 8845. The sequence comprises many C residues, so Clark anticipates the claim. The sequence was isolated as a lambda phage clone, so it Clark discloses the complement of the sequence as required by claim 53. See e.g. page 7900, Fig. 3.

Claims 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No.G10509, published 8/15/95).

GenBank Accession No.G10509 teaches a sequence tagged site that is identical to bases 8340-8903 of SEQ ID NO:2. See page 5 of previous Action issued 3/26/03. This sequence comprises a segment in excess of 250 bases having identity to SEQ ID NO:2 and comprising C residues. The sequence was initially obtained as a PCR fragment, so it was double stranded and contained a complementary sequence. For this reason the isolate contained the complement recited in claim 53.

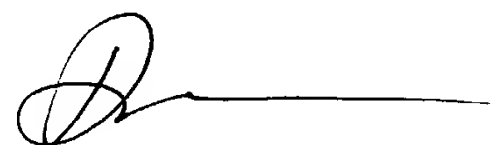
These rejections may be overcome by deleting the phrase, "the nucleotide corresponding to the nucleotide at".

Conclusion

Claim 34 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.



DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.